NICE guidance

Endovascular stent insertion for intracranial atherosclerotic disease

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg429

This guidance replaces IPG233.

1 Guidance

This document replaces previous guidance on endovascular stent insertion for intracranial atherosclerotic disease (interventional procedure guidance 233).

1.1 Current evidence on the efficacy of endovascular stent insertion for intracranial atherosclerotic disease shows no substantial differences in clinical outcomes compared with medical treatment after 1–2 years. Evidence on its safety shows that there is a significant risk of periprocedural stroke and death. Therefore, this procedure should only be used in the context of research. Research should clearly define patient selection and be designed to provide outcome data based on follow-up of at least 2 years.

2 The procedure

2.1 Indications and current treatments

2.1.1 Intracranial atherosclerotic disease is the narrowing or obstruction of arteries within the skull that supply blood to the brain. It is caused by atheromatous plaques, which can reduce blood flow and may be associated with thrombosis or embolism, leading to transient ischaemic attacks (TIA), stroke or death. Intracranial atherosclerotic disease is usually diagnosed only after a patient has presented with a TIA or stroke.

2.1.2 Symptomatic intracranial atherosclerotic disease is usually treated with antiplatelet medication together with a statin and attention to risk factors for atherosclerosis such as smoking, hypertension and diabetes.

2.1.3 Direct intervention to treat intracranial atherosclerotic disease is not commonly used. It involves balloon angioplasty to dilate diseased arteries, which may then be followed by stent insertion, with the aim of improving patency compared with balloon angioplasty alone.

2.2 Outline of the procedure

2.2.1 The procedure is carried out with the patient under general or local anaesthesia. Under fluoroscopic control, a catheter is introduced percutaneously through an artery in the arm or leg and guided into the affected intracranial artery. Balloon angioplasty of the target lesion is normally done to dilate it before inserting a stent. It is possible to insert more than 1 stent or to treat more than 1 lesion in a treatment session.

2.2.2 Two main types of stent have been used – balloon expandable and self-expanding. Some studies have also used drug-eluting stents. The technology has evolved over the past decade and continues to do so.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3 Efficacy

2.3.1 The efficacy outcomes described below include stroke or death occurring more than 30 days after the procedure (unless specified otherwise). Stroke or death occurring on or before 30 days is considered to be a safety outcome.

2.3.2 A randomised controlled trial of 451 patients treated by angioplasty and stent insertion or medical management alone reported ischaemic stroke in the area of the brain supplied by the artery with the index lesion more than 30 days after enrolment in 6% of patients in both groups (13/224 and 13/227, respectively, p value not stated) at a mean follow-up of 12 months. A case series of 213 patients reported lesion-related ischaemic stroke more than 30 days after the procedure in 3% (7/213) of patients, at a mean follow-up of 27 months. A case series of 158 patients reported that 20% (22/110) of patients had a stroke or TIA between 30 days and 12 months after the procedure.

2.3.3 The randomised controlled trial of 451 patients treated by angioplasty and stent insertion or medical management alone reported a death rate of 3% in both groups (7/224 and 7/227, respectively, p=0.95) at a mean follow-up of 12 months.

2.3.4 A systematic review comparing 36 studies of angioplasty and endovascular stent insertion with 33 studies of angioplasty alone reported stroke and/or death in 12% (123/1070) and 17% (125/731) of patients respectively at 1-year follow-up (p=0.0002).

2.3.5 The case series of 213 patients reported an overall restenosis rate of 19% (19/99) identified on follow-up angiography at a mean follow-up of 9 months. A case series of 189 patients reported recurrent stenosis in 25% (43/174) of lesions identified on angiography at a mean follow-up of

4 months. A case series of 113 patients reported an overall restenosis rate of 18% (16/89; identified by transcranial doppler ultrasound or angiography) at a mean follow-up of 29 months.

2.3.6 The Specialist Advisers listed key efficacy outcomes as reduction in TIA or stroke frequency.

2.4 Safety

2.4.1 The randomised controlled trial of 451 patients treated by angioplasty and stent insertion or by medical management alone reported stroke or death within 30 days of enrolment in 15% (33/224) and 6% (13/227) of patients, respectively (p=0.002). There were 5 stroke-related deaths in the stent group and 1 non-stroke-related death in the medical management group. The systematic review comparing 36 studies of angioplasty and endovascular stent insertion with 33 studies of angioplasty alone reported stroke and/or death in 8% (104/1291) and 9% (91/1027) of patients respectively at 1-month follow-up (p=0.49).

2.4.2 Stent occlusion occurred in 4% (2/53) of patients treated by endovascular stent insertion in a non-randomised comparative study. One occlusion occurred 2 days after stent insertion and the patient had extracranial-intracranial bypass surgery because of recurrent TIAs. The second occlusion occurred 9 days after stent insertion in a patient who was not receiving antiplatelet medication because of a gastrointestinal haemorrhage; the patient had a stroke and died.

2.4.3 Vessel rupture during stent navigation was reported in 2% (2/113) of patients in the case series of 113 patients; 1 patient died of massive subarachnoid haemorrhage, and the other was treated by emergency craniotomy and surgical clipping of the middle cerebral artery. One patient died after vessel rupture during the procedure in the case series of 189 patients.

2.4.4 Fatal intracerebral haemorrhage was reported in 1 patient in the case series of 189 patients (timing not reported). There were haemorrhages in 3 other patients; 1 intracerebral haemorrhage 6 days after the procedure (resolved within 30 days) and 2 subarachnoid haemorrhages (1 resolved

without treatment and the other was successfully treated by coil occlusion). Bilateral intracerebral haemorrhage was reported in 1 patient in the case series of 113 patients, 2 weeks after the procedure (no other details provided). Symptomatic subarachnoid haemorrhage (not otherwise described) was reported in 1% (2/213) of patients and symptomatic brain haemorrhage (not otherwise described) was reported in 1 patient, within 30 days of the procedure, in the case series of 213 patients.

2.4.5 Specialist Advisers listed anecdotal adverse events as basilar artery rupture resulting in death, disabling thalamic infarction, and reperfusion haemorrhage. They stated that theoretical adverse events included vessel dissection, embolisation, myocardial infarction, groin haematoma and contrast reactions.

2.5 Other comments

2.5.1 The Committee noted that a number of different devices have been used for endovascular stent insertion for intracranial atherosclerotic disease and that technical evolution of devices is continuing.

2.5.2 The Committee also noted that medical management is variable and continues to evolve. This complicates interpretation of studies that compare the procedure with medical treatment.

3 Further information

3.1 For related NICE guidance see www.nice.org.uk.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedures guidance process.

It updates and replaces NICE interventional procedure guidance 233.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Your responsibility
This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

permission of NICE.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation